K040674

JUN 3 0 2004

anthogyr

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

1. GENERAL INFORMATION

Submitter	ANTHOGYR (Registration number 802 0776) 164 rue des trois lacs 74700 SALLANCHES FRANCE Phone: 33(0)4 50 58 02 37 Fax: 33(0)4 50 93 78 60
Contacts	Eric GENEVE (RD Manager) e.geneve.rd@anthogyr.com Regulatory Affairs: Idée Consulting (Dr Isabelle DRUBAIX) idrubaix@nordnet.fr
Common Name	Dental handpiece and accessories
Classification Name	Handpiece, Contra- and Right-angle attachment, dental
Class	I
Product Code	EGS
CFR section	872.4200
Device panel	DENTAL
ANTHOGYR Trade Names	1. Surgi Control (Implantology Contra angles) 2. Endo Micro NiTi & NiTi Control (Endodontic Contra angles) 3. General dentistry Contra angles
Legally marketed predicate devices	1. Aseptico Autoclavable Handpieces (Aseptico) K020137 2. Aseptico Autoclavable Handpieces (Aseptico) K020137 3. Aseptico Autoclavable Handpieces (Aseptico) K020137, Series Xe, Se, Te (Micro Mega) K 971350

2. INTENDED USE

ANTHOGYR contra angles and handpieces are autoclavable devices intended for a wide range of procedures including implantology, endodontic surgeries and general dentistry.

3. DEVICE DESCRIPTION

ANTHOGYR has developed a full range of reducing, multiplying and 1:1 contra angle and right hand-piece intended to be used in implantology, endodontic and general dentistry procedures. ANTHOGYR Contra angles design, size and performance conform to NF EN ISO 7785-2 "Dental Handpieces – Part 2: Straight and geared angle handpieces.

4. PERFORMANCE DATA

ANTHOGYR Contra angles & Handpieces conform to the following voluntary Consensus standards:

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 3 0 2004

Mr. Eric Geneve
RD Manager
Anthogyr
164 Rue Des 3 Lacs
74700 Sallanches
FRANCE

Re: K040674
Trade/Device Name: ANTHOGYR Contra Angles and Handpieces
Regulation Number: 872.4200
Regulation Name: Dental Handpiece and Accessories
Regulatory Class: I
Product Code: EFA
Dated: March 8, 2004
Received: April 16, 2004

Dear Mr. Geneve:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

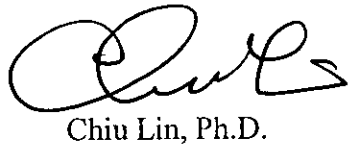
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

anthogyr

510(k) Number (if known): K040674

Device Name: ANTHOGYR CONTRA ANGLES AND HANDPIECES

Indications for Use: ANTHOGYR's fully autoclavable contra-angles and handpieces are devices intended for a wide range of dental procedures including:

- Endodontic surgeries, such as root canal preparations
- Implant surgery such as perforating the bone, tapping and threading procedures
- General dentistry such as removing carious material, cavity and crow preparation, finishing tooth preparations, restorations and polishing teeth

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K040674

Prescription Use _1_ **or** **Over-the-Counter Use**

(PER 21 CFR 801.109)

(Optional Format 1-2-96)